Complete Summary

GUIDELINE TITLE

Standards of medical care in diabetes.

BIBLIOGRAPHIC SOURCE(S)

Standards of medical care in diabetes. Diabetes Care 2004 Jan;27(Suppl 1):S15-35. [129 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Diabetes mellitus

- Type 1 diabetes
- Type 2 diabetes
- Other specific types of diabetes (due to other causes, e.g., genetic defects in beta-cell function, genetic defects in insulin action, diseases of the exocrine pancreas, drug or chemical induced)
- Gestational diabetes mellitus

GUIDELINE CATEGORY

Diagnosis
Management
Screening
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide clinicians, patients, researchers, payers, and other interested persons with the components of diabetes care, treatment goals, and tools to evaluate the quality of care

TARGET POPULATION

Screening

- Individuals at risk of developing diabetes mellitus
- Pregnant women

Diagnosis/Treatment/Management

- Individuals with type 1 diabetes mellitus
- Individuals with type 2 diabetes mellitus
- Individuals with other specific types of diabetes
- Pregnant women with gestational diabetes

INTERVENTIONS AND PRACTICES CONSIDERED

Screening/Diagnosis

1. Medical history
    - Signs and symptoms
    - Risk assessment
2. Physical examination
3. Laboratory evaluation
    - Glycated hemoglobin (A1C) testing
    - Fasting lipid profile, including total cholesterol, high-density lipoprotein cholesterol, triglycerides, and low-density lipoprotein cholesterol
    - Test for microalbuminuria
    - Serum creatinine

- Thyroid-stimulating hormone
- Electrocardiogram (ECG) in adults
- Urinalysis for ketones, protein, sediment

4. Specialist referrals as needed

Treatment/Management

1. Glycemic control
   - A1C testing
   - Patient education in self-monitoring of blood glucose
2. Medical nutrition therapy
   - Referral to dietician
3. Physical activity program
4. Management of complications
   - Cardiovascular disease
5. Blood pressure control
   - Lifestyle and behavior therapy
   - Drug therapy including angiotensin-converting enzyme (ACE) inhibitors, beta blockers, diuretics, angiotensin receptor blockers (ARBs)
   - Laboratory tests to monitor renal function and serum potassium levels
6. Lipid management with lifestyle modification (e.g., diet, exercise, smoking cessation) and pharmacological therapy (e.g., statins, fibrates, niacin)
7. Aspirin therapy
8. Smoking cessation counseling
9. Exercise stress testing, stress ECG and/or stress echocardiography and/or perfusion imaging
10. Refer to cardiologist
11. Nephropathy
    - Testing for microalbuminuria
    - ACE inhibitors, ARBs, dihydropyridine calcium channel blockers (DCCBs), non-DCCBs, beta blockers, diuretics
    - Protein restrictions
12. Diabetic retinopathy
    - Dilated and comprehensive eye examination
    - Laser therapy
13. Foot care
    - Examination, including Semmes-Weinstein monofilament, tuning fork, palpation, and visual examination
    - Patient education
    - Assessment for peripheral arterial disease using ankle-brachial index
    - Referral to specialist
14. Preventive Care
    - Preconception care for women
    - Immunization, including influenza and pneumococcal vaccines

MAJOR OUTCOMES CONSIDERED

- Rate of progression to type 2 diabetes
- Morbidity and mortality rates associated with diabetes
- Glycemic control during pregnancy to minimize the risk of fetal malformations and maternal and fetal complications in pregnant women with diabetes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations have been assigned ratings of A, B or C, depending on the quality of evidence (see table below). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an "A" rating are based on large, well-designed clinical trials or well done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they

are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

American Diabetes Association's evidence grading system for clinical practice recommendations:

A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence, i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford*

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations were reviewed and approved by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grading system for clinical practice recommendations (A through C, E) is defined at the end of the "Major Recommendations" field.

Note that these recommendations should be supplemented with specific recommendations detailed in related guidelines available from the American Diabetes Association; refer to the "Companion Documents" field in this summary for additional information.

Classification, Diagnosis, and Screening

Note: The complete criteria for the diagnosis of diabetes in nonpregnant adults are shown in Table 2 in the original guideline document.

- The fasting plasma glucose is the preferred test to screen for and diagnose diabetes in children and nonpregnant adults. (E)
- Screen for diabetes in high-risk, asymptomatic, undiagnosed adults and children within the health care setting. (E)
- In those with prediabetes (impaired fasting glucose/impaired glucose tolerance), lifestyle modification should be strongly recommended and progression of glycemic abnormalities followed by screening at least yearly. (A)
- Screen for diabetes in pregnancy using risk factor analysis and screening tests as noted; the oral glucose tolerance test is the preferred screening test in pregnancy. (E)

Initial Evaluation/Management

- Lowering glycated hemoglobin (A1C) has been associated with a reduction of microvascular and neuropathic complications of diabetes. (A)

- Develop or adjust the management plan to achieve normal or near-normal glycemia with an A1C goal of <7%. (B)
- More stringent goals (i.e., a normal A1C, <6%) can be considered in individual patients. (B)
- Lowering A1C may lower the risk of myocardial infarction and cardiovascular death. (B)
- Aggressive glycemic management with insulin may reduce morbidity in patients with severe acute illness, perioperatively and following myocardial infarction. (B)
- Less stringent treatment goals may be appropriate for patients with a history of severe hypoglycemia, patients with limited life expectancies, very young children or older adults, and individuals with comorbid conditions. (E)

Assessment of Glycemic Control

Self-monitoring of Blood Glucose

- Self-monitoring of blood glucose (SMBG) is an integral component of diabetes therapy. (B)
- Include SMBG in the management plan. (E)
- Instruct the patient in SMBG and routinely evaluate the patient´s technique and ability to use data to adjust therapy. (E)

Glycated Hemoglobin Test (A1C)

Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control) and quarterly in patients whose therapy has changed or who are not meeting glycemic goals. (E)

Medical Nutrition Therapy (MNT)

People with diabetes should receive individualized medical nutrition therapy as needed to achieve treatment goals, preferably provided by a registered dietician familiar with the components of diabetes medical nutrition therapy. (B)

Physical Activity

A regular physical activity program, adapted to the presence of complications, is recommended for all patients with diabetes who are capable of participating. (B)

Prevention and Management of Diabetes Complications

Blood Pressure Control

Screening and Diagnosis

- Blood pressure should be measured at every routine diabetes visit. Patients found to have systolic blood pressure $\geq$130 or diastolic blood pressure $\geq$80 mmHg should have blood pressure confirmed on a separate day. (C)

Goals

- Patients with diabetes should be treated to a systolic blood pressure <130 mmHg. (B)
- Patients with diabetes should be treated to a diastolic blood pressure <80 mmHg. (B)

Treatment

- Patients with hypertension (systolic blood pressure ≥140 or diastolic blood pressure ≥90 mmHg) should receive drug therapy in addition to lifestyle and behavioral therapy. (A)
- Multiple drug therapy (two or more agents at proper doses) is generally required to achieve blood pressure targets. (B)
- Patients with a systolic blood pressure of 130 to 139 mmHg or a diastolic blood pressure of 80 to 89 mmHg should be given lifestyle and behavioral therapy alone for a maximum of 3 months and then, if targets are not achieved, in addition, be treated with pharmacological agents that block the renin-angiotensin system. (E)
- Initial drug therapy for those with a blood pressure >140/90 mmHg should be with a drug class demonstrated to reduce cardiovascular disease (CVD) events in patients with diabetes (angiotensin converting enzymes [ACE] inhibitors, angiotensin receptor blockers [ARBs], beta-blockers, diuretics, and calcium channel blockers). (A)
- All patients with diabetes and hypertension should be treated with a regimen that includes either an ACE inhibitor or ARB. If one class is not tolerated, the other should be substituted. If needed to achieve blood pressure targets, a thiazide diuretic should be added. (E)
- If ACE inhibitors, ARBs, or diuretics are used, monitor renal function and serum potassium levels. (E)
- While there are no adequate head-to-head comparisons of ACE inhibitors and ARBs, there is clinical trial support for each of the following statements:
    - In patients with type 1 diabetes, with hypertension and any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy. (A)
    - In patients with type 2 diabetes, hypertension, and microalbuminuria, ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria. (A)
    - In those with type 2 diabetes, hypertension, macroalbuminuria, and renal insufficiency, ARBs have been shown to delay the progression of nephropathy. (A)
- In elderly hypertensive patients, blood pressure should be lowered gradually to avoid complications. (E)
- Patients not achieving target blood pressure despite multiple drug therapy should be referred to a physician experienced in the care of patients with hypertension. (E)
- Orthostatic measurement of blood pressure should be performed in people with diabetes and hypertension when clinically indicated. (E)

Lipid Management

Screening

- In adult patients, test for lipid disorders at least annually and more often if needed to achieve goals. In adults with low-risk lipid values (low-density lipoprotein [LDL]<100 mg/dL, high-density lipoprotein [HDL] >50 mg/dL, and triglycerides <150 mg/dL), repeat lipid assessments every 2 years. (E)
- In children >2 years of age, perform a lipid profile after diagnosis of diabetes and when glucose control has been established.
    - Type 1 diabetes: Begin prior to puberty, if positive family history of CVD (or if family history is unknown), and at puberty, if family history is known and is negative.
    - Type 2 diabetes: Begin at diagnosis, regardless of pubertal status.
    - If lipid values are considered low risk, repeat lipid profile every 2 to 5 years based on CVD risk status.

Treatment and Goals

- Lifestyle modification focusing on the reduction of saturated fat and cholesterol intake, weight loss, increased physical activity, and smoking cessation has been shown to improve the lipid profile in patients with diabetes. (A)
- Patients who do not achieve lipid goals with lifestyle modifications require pharmacological therapy. (A)
- Lower LDL cholesterol to <100 mg/dL (2.6 mmol/L) as the primary goal of therapy for adults. (B)
- Lowering LDL cholesterol with a statin is associated with a reduction in cardiovascular events. (A)
- In people with diabetes over the age of 40 with a total cholesterol $\geq$135 mg/dL, statin therapy to achieve an LDL reduction of approximately 30% regardless of baseline LDL levels may be appropriate. (A)
- In children and adolescents with diabetes, LDL cholesterol should be lowered to <100 mg/dL (2.60 mmol/L) using diet as well as medications based on LDL level and other cardiovascular risk factors in addition to diabetes. (E)
- Lower triglycerides to <150 mg/dL (1.7 mmol/L) and raise HDL cholesterol to >40 mg/dL (1.15 mmol/L). In women, an HDL goal 10 mg/dL higher may be appropriate. (C)
- Lowering triglycerides and increasing HDL cholesterol with a fibrate are associated with a reduction in cardiovascular events in patients with clinical CVD, low HDL and near-normal levels of LDL. (A)
- Combination therapy employing statins and fibrates or niacin may be necessary to achieve lipid targets but have not been evaluated in outcomes studies for either event reduction or safety. (E)

Anti-platelet Agents in Diabetes

- Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of myocardial infarction, vascular bypass procedure, stroke or transient ischemic attack, peripheral vascular disease, claudication, and/or angina. (A)
- Use aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 2 diabetes at increased cardiovascular risk, including those who are over 40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, albuminuria). (A)

- Use aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 diabetes at increased cardiovascular risk, including those who are over 40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, albuminuria). (C)
- People with aspirin allergy, bleeding tendency, receiving anticoagulant therapy, recent gastrointestinal bleeding, and clinically active hepatic disease are not candidates for aspirin therapy. Other antiplatelet agents may be a reasonable alternative for patients with high risk. (E)
- Aspirin therapy should not be recommended for patients under the age of 21 years because of the increased risk of Reye's syndrome associated with aspirin use in this population. People under the age of 30 have not been studied. (E)

Smoking Cessation

- Advise all patients not to smoke. (A)
- Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care. (B)

Coronary Heart Disease (CHD) Screening and Treatment

- Perform exercise stress testing in asymptomatic diabetic patients based on the criteria outlined in the original guideline document. Consider a risk factor–based strategy for the diagnosis of coronary artery disease (CAD) that might include stress electrocardiogram and/or stress echocardiography and/or perfusion imaging. (E)
- Refer patients with signs and symptoms of CVD or with positive noninvasive test for coronary artery disease to a cardiologist for further evaluation. (E)
- In patients with treated congestive heart failure, metformin use is contraindicated. The thiazolidinediones are associated with fluid retention, and their use can be complicated by the development of congestive heart failure. Caution in prescribing thiazolidinediones in the setting of known congestive heart failure or other heart diseases as well as in patients with preexisting edema or concurrent insulin therapy is required. (E)
- In patients >55 years of age, with or without hypertension but with another cardiovascular risk factor (history of CVD, dyslipidemia, microalbuminuria, smoking), an ACE inhibitor (if not contraindicated) should be considered to reduce the risk of cardiovascular events. (A)
- In patients with a prior myocardial infarction or in patients undergoing major surgery, beta-blockers, in addition, should be considered to reduce mortality. (A)

Nephropathy Screening and Treatment

General Recommendations

- To reduce the risk and/or slow the progression of nephropathy, optimize glucose control. (A)
- To reduce the risk and/or slow the progression of nephropathy, optimize blood pressure control. (A)

Screening

Perform an annual test for the presence of microalbuminuria in type 1 diabetic patients with diabetes duration of $\geq$5 years and in all type 2 diabetic patients, starting at diagnosis. (E)

Treatment

- In the treatment of both micro- and macroalbuminuria, either ACE inhibitors or ARBs should be used. (A)
- While there are no adequate head-to-head comparisons of ACE inhibitors and ARBs, there is clinical trial support for each of the following statements:
    - In patients with type 1 diabetes, with hypertension and any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy. (A)
    - In patients with type 2 diabetes, hypertension, and microalbuminuria, ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria. (A)
    - In patients with type 2 diabetes, hypertension, macroalbuminuria, and renal insufficiency (serum creatinine >1.5 mg/dL), ARBs have been shown to delay the progression of nephropathy. (A)
    - If one class is not tolerated, the other should be substituted. (E)
- With presence of nephropathy, initiate protein restriction to $\leq$0.8 g x kg^{-1} body wt^{-1} x day^{-1} (approximately 10% of daily calories), the current adult recommended dietary allowance for protein. Further restriction may be useful in slowing the decline of glomerular filtration rate (GFR) in selected patients. (B)
- With regards to slowing the progression of nephropathy, the use of dihydropyridine calcium channel blockers (DCCBs) as initial therapy is not more effective than placebo. Their use in nephropathy should be restricted to additional therapy to further lower blood pressure in patients already treated with ACE inhibitors or ARBs. (B)
- In the setting of albuminuria or nephropathy, in patients unable to tolerate ACE inhibitors and/or ARBs, consider the use of non-DCCBs, beta-blockers, or diuretics for the management of blood pressure. (E)
- If ACE inhibitors, ARBs, or diuretics are used, monitor serum potassium levels for the development of hyperkalemia. (B)
- Consider referral to a physician experienced in the care of diabetic renal disease when the estimated glomerular filtration rate (eGFR) has fallen to <60 mL x min^{-1} x 1.73 m^{-2} or if difficulties occur in the management of hypertension or hyperkalemia. (B)

Diabetic Retinopathy Screening and Treatment

General Recommendations

- Optimal glycemic control can substantially reduce the risk and progression of diabetic retinopathy. (A)
- Optimal blood pressure control can reduce the risk and progression of diabetic retinopathy. (A)
- Aspirin therapy does not prevent retinopathy or increase the risks of hemorrhage. (A)

Screening

- Adults and adolescents with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 3 to 5 years after the onset of diabetes. (B)
- Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes. (B)
- Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management. Less frequent exams (every 2–3 years) may be considered with the advice of an eye care professional in the setting of a normal eye exam. Examinations will be required more frequently if retinopathy is progressing. (B)
- When planning pregnancy, women with preexisting diabetes should have a comprehensive eye examination and should be counseled on the risk of development and/or progression of diabetic retinopathy. Women with diabetes who become pregnant should have a comprehensive eye examination in the first trimester and close follow- up throughout pregnancy and for 1 year postpartum. This guideline does not apply to women who develop gestational diabetes mellitus because such individuals are not at increased risk for diabetic retinopathy. (B)

Treatment

- Laser therapy can reduce the risk of vision loss in patients with high-risk characteristics. (A)
- Promptly refer patients with any level of macular edema, severe nonproliferative diabetic retinopathy, or any proliferative diabetic retinopathy to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy. (A)

Foot Care

- A multidisciplinary approach is recommended for persons with foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation. (A)
- The foot examination can be accomplished in a primary care setting and should include the use of a Semmes-Weinstein monofilament, tuning fork, palpation, and a visual examination. (B)
- Educate all patients, especially those with risk factors, including smoking, or prior lower-extremity complications, about the risk and prevention of foot problems and reinforce self-care behavior. (B)
- Refer high-risk patients to foot care specialists for ongoing preventive care and life-long surveillance. (C)
- Initial screening for peripheral arterial disease (PAD) should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ankle-brachial index (ABI), as many patients with peripheral arterial disease are asymptomatic. (C)
- Refer patients with significant claudication or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options. (C)

- Perform a comprehensive foot examination annually on patients with diabetes to identify risk factors predictive of ulcers and amputations. Perform a visual inspection of patientsÂ´ feet at each routine visit. (E)

Preventive Care

Preconception Care

- A1C levels should be normal or as close to normal as possible (<1% above the upper limits of normal) in an individual patient before conception is attempted. (B)
- All women with diabetes and childbearing potential should be educated about the need for good glucose control before pregnancy. They should participate in family planning. (E)
- Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy, and CVD. (E)
- Among the drugs commonly used in the treatment of patients with diabetes, statins are pregnancy category X and should be discontinued before conception if possible. ACE inhibitors and ARBs are category C in the first trimester (maternal benefit may outweigh fetal risk in certain situations), but category D in later pregnancy, and should generally be discontinued prior to pregnancy. Among the oral antidiabetic agents, metformin and acarbose are classified as category B and all others as category C; potential risks and benefits of oral antidiabetic agents in the preconception period must be carefully weighed, recognizing that sufficient data are not available to establish the safety of these agents in pregnancy. They should generally be discontinued in pregnancy. (E)

Immunization

- Annually provide an influenza vaccine to all diabetic patients 6 months of age or older. (C)
- Provide at least one lifetime pneumococcal vaccine for adults with diabetes. A one-time revaccination is recommended for individuals >64 years of age previously immunized when they were <65 years of age if the vaccine was administered >5 years ago. Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immunocompromised states, such as transplantation. (C)

Definitions:

American Diabetes Association's evidence grading system for clinical practice recommendations:

A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial

- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence, i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford*

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Decreased rate of progression to type 2 diabetes
    - Modest weight loss and regular physical activity can reduce rates of progression of impaired glucose tolerance to type 2 diabetes.
    - Regular exercise may prevent type 2 diabetes in high-risk individuals.
    - Drug therapy (metformin, acarbose, and orlistat) has been shown to be effective in reducing progression to diabetes in single trials, though generally not as effective as intensive lifestyle interventions.
- Decreased morbidity and mortality rates associated with diabetes
    - Prospective randomized clinical trials have shown that improved glycemic control is associated with decreased rates of retinopathy, nephropathy, and neuropathy, and epidemiological studies support the potential of intensive glycemic control in the reduction of cardiovascular disease.
    - Regular exercise has been shown to improve blood glucose control, reduce cardiovascular risk factors, contribute to weight loss, and improve well-being.
    - Lowering of blood pressure with regimens based on anti-hypertensive drugs including angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, beta-blockers, diuretics, and calcium channel blockers has been shown to be effective in lowering cardiovascular events and/or, in some studies, slowing progression of nephropathy and retinopathy.
    - Aspirin therapy has been used as a primary and secondary therapy to prevent cardiovascular events in diabetic and nondiabetic individuals.
    - Lipid management aimed at lowering low-density lipoprotein cholesterol, raising high-density lipoprotein cholesterol, and lowering triglycerides has been shown to reduce macrovascular disease and mortality in patients with type 2 diabetes, particularly those who have had prior cardiovascular events.
    - Intensive diabetes management with the goal of achieving near normoglycemia has been shown in large prospective randomized studies to delay the onset of microalbuminuria and the progression of microalbuminuria to macroalbuminuria in patients with type 1 and type 2 diabetes and to prevent and/or delay the onset of diabetic retinopathy.
    - Based on a case-control study, influenza vaccine has been shown to reduce diabetes-related hospital admission by as much as 79% during flu epidemics.
- Decreased congenital malformations in children of diabetic mothers
    - In several studies, women who participated in preconception diabetes care programs had lower incidence of major congenital malformations than women who did not participate.

POTENTIAL HARMS

- Intensive glycemic control has been found to increase risk of hypoglycemia and weight gain.
- Combination therapy, with a statin and a fibrate or statin and niacin, is associated with an increased risk for abnormal transaminase levels, myositis, or rhabdomyolysis.
- Given the risk of a modest loss of visual acuity and of contraction of visual field from panretinal laser surgery, such therapy has been primarily recommended for eyes approaching or reaching high-risk characteristics.
- Older patients can be treated with the same drug regimens as younger patients, but special care is required in prescribing and monitoring drug therapy.

CONTRAINDICATIONS

CONTRAINDICATIONS

In older patients, metformin is often contraindicated because of renal insufficiency or heart failure.

In patients with treated congestive heart failure, metformin use is contraindicated.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Evidence is only one component of clinical decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and above all, patient´s values and preferences, must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by the American Diabetes Association, may miss some nuances that are important in diabetes care. For example, while there is excellent evidence from clinical trials supporting the importance of achieving glycemic control, the optimal way to achieve this result is less clear. It is difficult to assess each component of such a complex intervention.
- While individual preferences, comorbidities, and other patient factors may require modification of goals, targets that are desirable for most patients with diabetes are provided. These standards are not intended to preclude more extensive evaluation and management of the patient by other specialists as needed.
- Glycemic control. A major limitation to the available data is that they do not identify the optimum level of control for particular patients, as there are individual differences in the risks of hypoglycemia, weight gain, and other adverse effects. Furthermore, with multifactorial interventions, it is unclear how different components (e.g., educational interventions, glycemic targets, lifestyle changes, and pharmacological agents) contribute to the reduction of complications. There are no clinical trial data available for the effects of glycemic control in patients with advanced complications, the elderly ($\geq$ 65 years of age), or young children (<13 years of age).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

In recent years, numerous health care organizations, ranging from large health care systems such as the U.S. Veterans Administration to small private practices, have implemented strategies to improve diabetes care. Successful programs have published results showing improvement in important outcomes, such as glycated hemoglobin measurements, as well as process measures, such as provision of eye exams. Features of successful programs reported in the literature include:

- Adoption of practice guidelines, with participation of the providers in the process. Guidelines should be readily accessible at the point of service, such as on patient charts, in examining rooms, or on office computer systems.
- Systems changes, such as provision of automated reminders to providers and patients, profiling or reporting of data to providers, and identification of patients at risk because of abnormal target values or a lack of reported values.
- Practice changes, such as scheduling of dedicated diabetes visits and group visits.
- Delivery of diabetes self-management education.
- Availability of case management services, usually by a nurse.
- Availability and involvement of expert consultants, such as endocrinologists and diabetes educators.
- Because these interventions are generally provided as components of a multifactorial intervention, it is difficult to assess the contribution of each component; however, it is clear that optimal diabetes management requires an organized, systematic approach and involvement of a health care team.
- Simple tools such as flow charts may be useful in smaller practices.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Standards of medical care in diabetes. Diabetes Care 2004 Jan;27(Suppl 1):S15-35. [129 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1988 (revised 2004 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

The American Diabetes Association received an educational grant from LifeScan, Inc., a Johnson and Johnson Company, to support publication of the 2004 Diabetes Care Supplement.

GUIDELINE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: Standards of medical care for patients with diabetes mellitus. Diabetes Care 2003 Jan;26(Suppl 1):S33-50.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus: Follow-up report on the diagnosis of diabetes mellitus. Diabetes Care 26:3160-3167, 2003.

Print copies: Available from the American Diabetes Association (ADA), 1701 North Beauregard Street, Alexandria, VA 22311.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 2, 2001. The information was verified by the guideline developer on August 24, 2001. This summary was updated by ECRI on March 14, 2002, July 29, 2003, and May 26, 2004.

COPYRIGHT STATEMENT

Date Modified: 11/15/2004